

(PCT Article 36 and Rule 70)

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/019437

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1, 4-19 as originally filed/furnished
- pages* 2-3, 3/1 received by this Authority on 26.10.2005
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-5 received by this Authority on 26.10.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/5-5/5 as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1-3</u>	YES
		Claims <u>4-5</u>	NO
	Inventive step (IS)	Claims _____	YES
		Claims <u>1-5</u>	NO
	Industrial applicability (IA)	Claims <u>1-5</u>	YES
		Claims _____	NO
2.	Citations and explanations (Rule 70.7)		
	<p>Document 1: US 2003-0118676 A (Council of Scientific and Industrial Research), 26 June 2003</p> <p>Document 2: JP 11-221048 A (Archer Daniels Midland Co.), 17 August 1999</p> <p>Document 3: JP 2003-63971 A (Tama Biochemical Co., Ltd.), 5 March 2003</p> <p>Document 4: JP 2002-541158 A (Hormos Nutraceutical OY Ltd.), 3 December 2002</p> <p>Document 5: Phytochemicals in Human Health Protection, Nutrition and Plant Defense, 1999, pages 51 to 65</p> <p>Document 6: JP 1-228928 A (Tsumura & Co.), 12 September 1989</p> <p>[1] The invention set forth in claims 4 and 5 lacks novelty in the light of documents 2 to 5 cited in the international search report.</p> <p>Document 2 (claims 18, 61 and 62) sets forth a food containing enterolactone.</p> <p>Document 3 (paragraphs [0016] and [0019]) sets forth a food containing a lignan precursor of enterolactone.</p> <p>Document 4 (claims 1 and 10; paragraph [0009]) sets forth a functional food containing a lignan precursor of</p>		

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enterolactone.

Document 5 (table 1) sets forth a food containing enterolactone.

In contrast, the food of the invention set forth in claims 4 and 5 is used "for improving fat metabolism abnormalities", and although this feature is not disclosed in documents 2 to 5, in the technical field of food, this food cannot be distinguished, even if the food is specified by functional properties.

[2] The invention set forth in claims 1 to 3 does not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 (tables 1 and 3) indicates that matairesinol which is a lignan precursor of enterolactone has an activity of suppressing the proliferation of hepatoma, therefore a person skilled in the art would be able to verify the activity of suppressing the proliferation of hepatoma of different types of lignan precursors similar to matairesinol as necessary.

Moreover, although document 1 does not set forth the apoptosis inducing activity, cell cycle stoppage activity and fat metabolism abnormality improving activity of said precursor, the applicable disorder for the composition set forth in claims 1 to 3 of this application is hepatoma, therefore the effect of the invention of this application is not particularly marked.

[3] The invention set forth in claims 1 to 5 does not involve an inventive step in the light of document 6 cited in the international search report.

Document 6 (claim 7) indicates that enterolactone

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has anti-cancer activity, therefore a person skilled in the art would be able to attempt to use said lactone in the treatment of hepatoma, which is a specific cancer, as necessary.

In addition, a person skilled in the art would be able to add the enterolactone set forth in document 6 to a food as necessary.

[4] The invention set forth in claims 1 and 2 does not involve an inventive step in the light of documents 2 to 5 cited in the international search report.

Documents 2 to 5 indicate that enterolactone or a lignan derivative of said lactone has anti-cancer activity, therefore a person skilled in the art could attempt to apply these compounds to the treatment of hepatoma, which is a specific cancer, as necessary.